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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Phillip D. Purdy

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11/07/2006

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/905,670

Applicant(s)

PURDY, PHILLIP D.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-13, 17-28 and 64-69 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10, 14-16 and 29-63 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66 is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-13, 17-22, 24-28, 64, 65 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 September 2006 has been entered.

### ***Claim Objections***

2. Claims 1,64,65,66,67, and 68 objected to because of the following informalities: there is inconsistent spelling in the word "subarchnoid" versus "subarachnoid" in the preamble versus the body of the claims. Examiner believes the correct spelling is "subarachnoid". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1,7,11,13,21,24,27,28,65 are rejected under 35 U.S.C. 102(b) as being anticipated by AEBISCHER (US 5,487,739).

Regarding claim 1, Aebischer teaches a method of navigating the subarachnoid space (Fig 2J, 116) comprising: percutaneously introducing a sufficiently flexible guidewire

(102) into the spinal subarachnoid space at an entry location (between L3 and L4); introducing a device over the guidewire (cannula 20), the device having a first passageway to slidably receive, and work with, at least the guidewire, and the guidewire being positioned in the passageway (See Cols 9-11, description of Figs 2A-2J); and advancing the device over the guidewire and within the spinal subarchnoid space at least more than 10 centimeters from the entry location (to site 12'). Regarding the distance to the treatment site, Aebischer discloses the use of a 4" (10.2 cm) Tuohy needle to introduce the guidewire and a 31" long guidewire. It is further disclosed that a tether (44) is 8-10cm long. As can be seen, especially in Figure 4, the tether extends from a point distal of the entry location to the treatment location, therefore requiring the guidewire to be advanced at least more than 10cm.

Regarding claim 7, the device (20) includes a second passageway (lumen of the dilator 104), configured to slidably receive and work with the guidewire (Fig 2E)

Regarding claim 11, a cross-section taken at the point where clip 60 crimps the device would be non-circular (Fig 3A).

Regarding claim 13, medication (pellet 80A) is delivered to an intracranial subarachnoid space.

Regarding claims 21 and 65, a penetration apparatus (100) is inserted through the first passageway of cannula (20) with an inner puncture element (100B) which is used to puncture the pia matter (Fig 4).

Regarding claim 24, the position of the device is monitored via radio-opaque material (Col 5 1<sup>st</sup> full paragraph).

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Regarding claim 27, material (pellet 80) is introduced and can be placed near a cranial nerve in order to treat a neurological condition.

Regarding claim 28, the material can be genetic (cells 26).

4. Claims 1,4,12,17,19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by CARROLL (US 6,761,715).

Regarding claim 1, Carroll teaches a method of navigating the subarachnoid space (Fig 6) comprising: percutaneously introducing a sufficiently flexible guidewire (60a and 60b) into the spinal subarachnoid space at an entry location (shown at T6, Fig 7); introducing a device over the guidewire (18), the device having a first passageway to slidably receive, and work with, at least the guidewire, and the guidewire being positioned in the passageway (Fig 3); and advancing the device over the guidewire and within the spinal subarachnoid space at least more than 10 centimeters from the entry location (to site 12'). Regarding the distance to the treatment site, Carroll discloses the use of a cryocatheter (18) of 6-36 inches. The introducer (10) has a length of 4-5 inches. Therefore, the catheter and guidewire are perfectly capable of being inserted at least more than 10cm.

Regarding claims 4,12,17 the cryocatheter (18) is used to induce hypothermia (thereby changing the temperature of at least some brain tissue) via cryothermal stimulation

Regarding claims 19,20 a temperature detector (50) is introduced with the catheter (18) and is used to monitor a physiological property

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of MICHAELI (US 6,328,694).

Aebischer teaches a method of inserting a device into the subarachnoid space and delivering a medication thereto. Aebischer does not teach removing a portion of the brain. However, in the placement of the dilator, catheter, and capsule, it would seem that a portion of the brain tissue would be removed. In light of Aebischer's silence on this point, Michaeli is referenced. Michaeli discusses a method of performing brain surgery wherein a portion of the brain is removed (Col 2, lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Aebischer to include the explicit teachings of removing brain tissue as taught by Michaeli in order to increase the chance of recovery for the rest of the brain and improve effectiveness of treatment.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer.

Aebischer does not explicitly teach the flushing of cerebrospinal fluid to remove blood, but does teach that a sample of fluid can be removed through the guidance needle and tested for the presence of CSF. It would have been obvious to one of ordinary skill in

the art at the time the invention was made to remove any blood present in the removed CSF in order to collect a more pure sample for testing.

8. Claims 5,6, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of BARBUT (US 6,379,331).

Aebischer fails to teach the method of accessing a ventricle in the head and draining that ventricle. Barbut teaches that a catheter is used to access a lateral ventricle that the catheters can be used to drain fluid from the body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the drainage steps of Barbut with the insertion steps of Aebischer in order to prevent inadvertent mixing of blood and CSF and to keep the surgical field clear.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of PUTZ (US 6,004,262).

Aebischer discloses a cannula inserted into the subarachnoid space and a dilator inserted into the space. Aebischer does not teach the use of an endoscope inserted into the dilator or cannula. Putz discloses the use of an endoscope to assist in navigation through the subarachnoid space (Col 3 line 33- Col 5 line 30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert an endoscope into the channel of the dilator of Aebischer in order to improve visualization of the surgical site and avoid errors in surgery.

10. Claims 8 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of KEEP (US 2004/0147433).

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Aebischer teaches the insertion of a medical pellet into the spinal subarachnoid space, but does not teach that the pellet is radioactive. Keep teaches that it is well known in the art to use a radioactive pellet in order to irradiate the cells of a tumor (P0017). . It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a radioactive pellet of Keep with the insertion method of Aebischer in order to deliver appropriate therapies to the patient.

11. Claims 25,26, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebischer in view of HOFMANN (US 6,330,466)

Aebischer discloses a cannula inserted into the subarachnoid space and a dilator inserted into the space. Aebischer does not teach the use of an electrode being placed near brain tissue. Aebischer's device is perfectly capable of inserting an electrode near brain tissue. Hofmann teaches that it is well known in the art to place electrodes near the brain for the purpose of stimulating or recording. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the insertion procedure of Aebischer in order to insert the electrode of Hofmann near the brain tissue in order to provide treatment to a patient.

***Allowable Subject Matter***

12. Claim 66 is allowed.

13. Claim 23 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Claims 23 and 66 have been indicated as allowable because it is not taught or suggested by the prior art of record to perform a method of navigating a spinal subarchnoid space in a living being, comprising: percutaneously introducing a guidewire into the spinal subarachnoid space at an entry location, the guidewire being sufficiently flexible to navigate the spinal subarachnoid space; percutaneously introducing a device over the guidewire and into the spinal subarachnoid space, the device having a first passageway sized to slidably receive, and work with, at least the guidewire, and the guidewire being positioned in the first passageway; and advancing the device within the spinal subarachnoid space at least more than 10 centimeters from the entry location, wherein the advancing is achieved via a robotic device.

### ***Response to Arguments***

14. Applicant's arguments with respect to claims 1-8, 11-13, 17-28 and 64-69 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

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11/6/06*

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